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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,566	03/08/2004	Clark R. Baker JR.	TYHC:0069/FLE (P0426R)	1089
52144	7590	07/02/2007		
Nelcor Puritan Bennett LLC c/o Fletcher Yoder PC P.O. BOX 692289 HOUSTON, TX 77269-2289			EXAMINER TOTH, KAREN E	
			ART UNIT 3735	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/796,566	Applicant(s) BAKER, CLARK R.	
	Examiner Karen E. Toth	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

2. Claims 1, 5, 8, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Diab (US Patent Application Publication 2002/0128544).

Regarding claim 1, Diab discloses a method comprising using a first and a second method to determine first and second heart rates from a pulse oximetry signal (paragraphs [0028], [0257], [0327]), evaluating the reliability of the first heart rate using metrics (paragraph [0322] – High Confidence Test Module 301), and using the first heart rate when the metrics indicate that the first method is reliable and using the second heart rate when the metrics indicate that the first method is unreliable (paragraphs [0328]-[0332], [0345]-[0347] – that is, the results of the confidence test are used to determine which method of signal processing is used to find the heart rate).

Regarding claim 5, Diab discloses a pulse oximeter that can be used to determine a heart rate (paragraphs [0019]-[0020], [0028]) comprising first and second heart rate calculators for determining first and second heart rates from a pulse oximetry signal using first (element 586) and second (element 590) methods (paragraphs [0257], [0327]-[0332]), an evaluator configured to determine the reliability of the first heart rate by applying metrics to the first method (High Confidence Test Module 301 – paragraph [0322]), and a selector configured to use the first heart rate when the metrics indicate

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that the first heart rate is reliable and the second heart rate when the metrics indicate that the first heart rate is unreliable (paragraphs [0332], [0345]-[0347]).

Regarding claims 8 and 10, Diab discloses a pulse oximetry system comprising a sensor adapted to provide a signal related to a physiological constituent (element 300; paragraphs [0019]-[0020], [0028]) and a monitor adapted to process the signal to determine a pulse period, the monitor comprising software adapted to process the signal to determine a first pulse period using a first method (element 586), software adapted to process the signal to determine a second pulse period using a second method (element 590), an evaluator configured to determine the reliability of the first pulse period by applying metrics to the first method (element 301), and a selector configured to use the first pulse period when the metrics indicate that the first method is reliable and the second period when the metrics indicate that the first method is unreliable (paragraphs [0327]-[0332], [0345]-[0347]). Diab's method converts a frequency spectrum, or pulse period, to a pulse rate.

Regarding claim 11, Diab discloses a method of determining a heart rate in a pulse oximeter (element 300; paragraphs [0019]-[0020], [0028]) comprising determining a first pulse period from a pulse oximetry signal using a first method (element 586) and a second pulse period from the signal using a second method (element 590) when metrics (element 301) indicate that the first pulse period is unreliable, and converting the first pulse period into a heart rate when the metrics indicate that it is reliable and converting the second pulse period into a heart rate when the metrics indicate that the first is unreliable (paragraphs [0327]-[0332], [0345]-[0347]).

Claim Rejections - 35 USC § 103

3. Claims 2, 6, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diab in view of Leon (US Patent 5365934).

Regarding claim 2, Diab discloses all the elements of the current invention, as described above, except for determining that the first heart rate is unreliable after a pulse is rejected.

Leon discloses a method of using multiple heart rate signals to determine an accurate heart rate where a first rate is considered unreliable after it is rejected, in favor of an alternate heart rate candidate (column 12, lines 46-52), in order to ensure that the most accurate heart rate is obtained. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Diab and considered the first heart rate to be unreliable after its rejection, as taught by Leon, in order to ensure that the most accurate heart rate is obtained.

Regarding claim 6, Diab discloses all the elements of the current invention, except for the selector determining that the first heart rate is unreliable when metrics indicate that a pulse is rejected.

Leon discloses using multiple heart rate signals to determine an accurate heart rate where a first rate is considered by a selector to be unreliable after it is rejected, in favor of an alternate heart rate candidate (column 12, lines 46-52), in order to ensure that the most accurate heart rate is obtained. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of

Diab and considered the first heart rate to be unreliable after its rejection, as taught by Leon, in order to ensure that the most accurate heart rate is obtained.

Regarding claim 12, Diab discloses all the elements of the current invention, as described above, except for determining that the first pulse period is unreliable after a pulse is rejected.

Leon discloses a method of using multiple pulse period signals to determine an accurate pulse period where a first pulse is considered unreliable after it is rejected, in favor of an alternate pulse period candidate (column 12, lines 46-52), in order to ensure that the most accurate pulse period is obtained. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Diab and considered the first pulse period to be unreliable after its rejection, as taught by Leon, in order to ensure that the most accurate pulse period is obtained.

4. Claims 3, 4, 7, 9, and 13 are rejected under 35 U.S.C. 103(a) as being obvious over Diab in view of Baker (US Patent Application Publication 2002/0137994).

Regarding claim 3, Diab discloses all the elements of the current invention, as described above, except for one of the methods of determining a heart rate using an ensemble averaged waveform.

Baker teaches using pulse oximetry to obtain heart rate signals where, as part of determining the most accurate heart rate signal, the pulse period of a particular set of signals (that is, an ensemble), may be averaged (paragraph [0057]), in order to determine an accurate heart rate. It would have been obvious to one of ordinary skill in

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the art at the time the invention was made to have made the method of Diab and chosen to use an ensemble averaged waveform, as taught by Baker, for one of the methods, such as the first one, since the technique is well known in the art for determining an accurate heart rate.

Regarding claim 4, Diab discloses all the elements of the current invention, as described above, except for determining the heart rate by determining a pulse period and converting it to a rate.

Baker teaches using pulse oximetry to obtain heart rate signals, where the signals are used to determine a pulse period (average period of the pleth), which is converted into a heart rate (pulse rate) (paragraph [0057]), in order to accurately monitor the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Diab and determined the heart rate from a pulse period, as taught by Baker, in order to accurately monitor the patient.

Regarding claim 7, Diab discloses all the elements of the current invention except for the first heart rate calculator using an ensemble averaged wave form and the second not. Baker further teaches using pulse oximetry to obtain heart rate signals where, as part of determining the most accurate heart rate signal, the pulse period of a particular set of signals (that is, an ensemble), may be averaged (paragraph [0057]), in order to determine an accurate heart rate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Diab and chosen to use an ensemble averaged waveform, as further taught by Baker, for one of

the methods, such as the first one, since the technique is well known in the art for determining an accurate heart rate.

Regarding claim 9, Diab discloses all the elements of the current invention, as described above, except for one of the methods of determining a pulse period using an ensemble averaged waveform.

Baker teaches using pulse oximetry to obtain physiological signals where, as part of determining the most accurate pulse period signal, the pulse period of a particular set of signals (that is, an ensemble), may be averaged (paragraph [0057]), in order to determine an accurate heart rate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Diab and chosen to use an ensemble averaged waveform, as taught by Baker, for one of the methods, such as the first one, since the technique is well known in the art for determining an accurate pulse period.

Regarding claim 11, Diab discloses all the elements of the current invention, as described above, except for one of the methods of determining a pulse period using an ensemble averaged waveform.

Baker teaches using pulse oximetry to obtain physiological signals where, as part of determining the most accurate pulse period signal, the pulse period of a particular set of signals (that is, an ensemble), may be averaged (paragraph [0057]), in order to determine an accurate heart rate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Diab and chosen to use an ensemble averaged waveform, as taught by Baker, for one of the

methods, such as the first one, since the technique is well known in the art for determining an accurate pulse period.

Response to Arguments

5. Applicant's arguments with respect to claims 1-7 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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